

Abstract:

Please cancel Abstract of record and substitute new Abstract with:

A single piece full arch adjustable dental impression tray is disclosed. The invented impression tray inner wall has a break. A connecting member, which supports inner and outer walls, also has a break. The impression tray has a continuous outer wall. Whereby breaks of both inner wall and connecting member allow for impression tray adjustment by manually reshaping the outer wall to accommodate different arch size widths.

Remarks

1. The claims of record have been all rewritten and replaced with new claims 3 to 7. These claims are submitted to be patentable over the cited references because they recite over novel structure and thus distinguishes over every reference, section 102. The physical distinctions effect greater efficiency. All adjustable impression trays of prior art are made of multiple pieces that are stabilized in fixed position by indexing or clamping. Those skilled in the art do not realize the potential of non-stabilized impression trays. Such unanchored devices would be deemed inaccurate by many skilled professionals. Thus, the claims of present invention are allowable and are unobvious under section 103.

The Claims All Distinguish Over The References Under Section 102

2. The two independent claims distinguish over the references under section 102. The claims recite a dental tray which is made from one piece. This one piece is adjustable by stretching at a specific forgiving point. The resultant residual form stands alone as the final sized dental tray. There is no means of fixation. All prior art adjustable trays use some type of clamping, holding or indexing means. Search of the prior art shows no tray that is adjustable by simple manipulation and not held by a pin, screw, index, clamp, or gear arrangement.
3. In U.S. Patent No. 1,652,910, Psayla discloses an adjustable impression tray with breaks in inner and outer wall. It is however held fast by pins and adjusting nuts. In use, Psayla discloses, the first step is to loosen nuts, 13. And when the adjustments are accomplished the nuts are tightened. When the nuts are tightened, the chart retains the shape of the tray. In all eight claims, Psayla writes of his arcuate members being pivotally connected or adjustably connected. This is referring to his specification where he specifies connections are made of pins and nuts. He does not mention any adjustment that can be self supported without a fixation means. Since he does not indicate anything other than traditional fixation it may be concluded that this inventor did not have the vision of a free standing tray. The application presented share similar features with Psayla that the examiner points out on page 3 of Office Action of June 24, 2004. However, the significant structural difference is that the current application does not possess a link which is held by nuts. Further, the present disclosure utilizes no stabilization. This is significant. The one piece design allows for efficient manufacturing for tray. It also allows for more efficient use by dentist, who may quickly adjust tray and perform so without need for tightening screws.
4. In U.S. Patent No. 1,054,999, Thein invents an adjustable dental impression tray. This tray is very effective in adjusting to various shapes of the dental arch. However, Thein relies on locking of movable components to hold settings of tray. It is inefficient for a dental practitioner to go back and tighten settings with fasteners once the tray is set to

position for use. It is also costly to produce parts for such a tray. Thein's tray would have parts that need to be assembled for initial use. The present disclosure is an improvement over Thein and other inventors because adjustment is made possible with use of a single piece molded tray. It is more efficient because there are no clamping devices to tighten after tray size is configured.

5. The present invention is more cost effective. This tray is made of one molded piece, not multiple pieces that are mated together with hinges as other inventors present. The present disclosure is a simpler device. No assembly of separate segments mating with fasteners is necessary. Accordingly, even a slight savings in manufacturing costs for a disposable impression tray would enhance commercial appeal.

6. In U.S. Patent No. 5,297,960, Burns invents an adjustable dual arch impression tray. The new tray design allows for longer arch length adjustment. This allows for arches that extend further distally than the norm, perhaps in cases where patients have retained wisdom teeth. However, the Burns invention does not adjust for molars that flare toward the buccal. Therefore, it does accommodate longer arches, but not wider arches. The adjustment available in Burns tray has a different characteristic than that of the present invention. The Burns tray would be limited in applications of wider arch configurations.

The Novel Physical Features Of The Claims Provide Enhanced Results And Hence Should Be Considered Unobvious, Making The Claims Patentable Under Section 103.

7. Applicant submits that the above recited features in the independent claims, and hence in all claims, provide better results (invented tray has no stabilization) and hence should be considered unobvious, making the claims patentable under section 103.

Unobviousness is supported for the following reasons:

- Many patients do present with arch forms that are amenable with present day impression trays. This is supportive of present techniques.
- An unfastened and locked tray gives unexpected results. Previous inventors have presented many variations of indexing and locking, but never a self supported tray. In actuality, this tray disclosed herein is even more accurate.
- Dental professionals do not readily accept the fact that this disclosed tray is accurate and reliable. It is a novel concept to have an unstabilized tray that is not secured or indexed in position. Individuals removed from this new approach would need convincing details before acceptance.
- It is not recognized in publications or professional opinion that the arch size discrepancy is predominantly in the posterior areas. It is assumed larger arches are larger throughout the entire arch. However, anterior arch areas have less variation in size. This invention relies on the unrecognized dental condition that the arch size discrepancy is much more significant in the posterior areas.

8. Impression trays of the present market come in varying sizes. However, the larger sizes are larger in all dimensions, so that a next size larger tray, for example, may fit the posterior, yet now is too large in the anterior. Most present-day manufacturers make this mistake. The inventor has not seen a deviation from this pattern, and it is the source for this disclosure.

9. At the outset, the inventor would cut a presently marketed tray in the middle and spread only the posterior portion. The tray was stabilized with methylmethacrylate. Later, trays were stabilized with peripheral wax. And later still trays were merely opened in the back and not stabilized at all. All of these progressive steps were performed over several

years. And all the time the resultant models were verified for accuracy with an invented device called a model checker, U.S. Patent No. 5, 924,862. This was the progression of the current disclosure and the reason for patent application. Thus, having an unstabilized impression tray would not be obvious to experts in the field. It would need to be proven to be accepted. The present inventor feels that this adds merit for acceptance by the examiner under section 103. In use, this unadjusted tray is more accurate than present techniques. This can be proven by anyone using a model checker. The accuracy is because:

- The tray better accommodates the shape of the arch. There is an even thickness of impression material encompassing the dentition.
- The tray is better able to flex, along with impression material, to break the vacuum seal. The impression is removed atraumatically and this creates less pull on impression. A rigid tray forces all compensating movement solely on the impression material itself.

10. In International Publication Number WO 03/020155 A1, inventor Skinner discloses an indexed adjustable tray. This tray will adjust to accommodate the wider posterior areas, but the tray also expands in the anterior area as well. The newly set configuration may in fact be too large for a comfortable anterior fit.

11. Skinner's tray is manufactured in two arcuate members and are movably connected together. He explains that movably connected refers to adjustment mechanisms such as post and shaft that possess mating engagement. His alternate preferred embodiment for the adjustment mechanism is concentric gears. He also mentions ball cap fasteners, ratchet strap fasteners, or other similar types of conventional fasteners. All of his ramifications are the same, that is, always inclusive of mating engagement or selective positioning. There is no presentation of a free self supported adjustable tray. In fact, no

inventor suggests this route for an adjustable tray. It is not intuitive that such a product would be reliable. The present inventor feels this is also supportive of unobviousness and would ask examiner to please consider all previous approaches to adjustable trays. Please recognize the original concepts presented herein and these concepts support an adjustable tray that is unanticipated. Please recognize no inventor or author anywhere presents a tray without indexing or clamping means anywhere in summaries or ramifications or articles. This is proof that no previous researcher has attempted this unique approach. The present inventor was only able to discover this novelty by use of a model checker. By diligence of verifying resultant model accuracy against tray design was inventor able to provide a better impression tray for professional use. Stock trays of present use will not provide the consistent accuracy of the present disclosure.

12. Skinner does suggest placement of notches in the outer wall. These are for purpose of breaking tray segments completely away to reduce overall size of impression tray. The notches are not for the purpose of flexing the shape of outside wall.

13. In France Patent No. FR 2551654 A1, Decrop reveals an adjustable tray. This tray works well to adjust to different size arches. However, it relies on a clamping device. Its different configurations are held fast by a screw. Once the desired shape is achieved by the dental practitioner, it is held by a locking device. The inventor fails to utilize a simpler approach as in the present invention.

14. Decrop's disclosure also hinges in the anterior midline of tray. This adjustment would accommodate a wider posterior segment, but also make a wider anterior segment. This would be undesirable in some cases. The present invention expands only in the posterior segment. This posterior adjustment quality of the present invention accommodates all arches in a more desirable overall fit throughout the entire arch.

Additional Reasons Supporting Unobviousness

15. Working models of the present invention were shared with a dental manufacturing company. This company may be the biggest participant in the specific area of disposable impression trays. The director has many years experience in the field and in contact with most of the dental universities. This director at first questioned the concept of accuracy of this new tray design to a significant degree. With the inventors diligence explaining the genesis of the concept and details of proof of performance the director finally accepted the tray design. This company is considering its commercial appeal.

The inventor has also shared working models with two local dentists. Both of these dentists gave favorable comments. They recognized the advantages and believed there would a market for such an improvement.

16. Lack of implementation: If the invention were in fact obvious, because of its advantages, those skilled in the art surely would have implemented it by now. Those skilled in the art have not implemented the invention, despite its great advantages, indicates that it is not obvious.

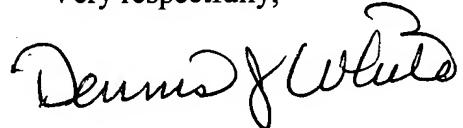
17. This invention solves a long existing, yet unsolved need for those patients seeking a superior process for dental impressions.

Request for Constructive Assistance

18. The undersigned has made a diligent effort to amend the claims of this application so that they define novel structure (manufacturers have never adequately addressed the problems of manufacturing an adjustable impression tray in an efficient manner) which is also submitted to render the claimed structure unobvious because it approaches impression tray adjustments with a novel design (unobviousness is pointed out over the existing prior art). If, for any reason the claims of this application are not believed to be

in full condition for allowance, applicant respectfully requests the constructive assistance and suggestions of the Examiner in making constructive suggestions pursuant to MPEP 706.03(d) in order that this application can be placed in allowable condition as soon as possible and without the need for further proceedings.

Very respectfully,



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